MISSOURI CIRCUIT COURT
TWENTY-SECOND JUDICIAL CIRCUIT
(CITY OF ST. LOUIS)

ROBERT CLARK, on behalf of TYRONE HEMPHILL, deceased,	)	
Plaintiff,	)	
v.	)	
JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC; JANSSEN ORTHO, LLC; JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER PHARMA AG; BAYER CORPORATION; BAYER HEALTHCARE, LLC; BAYER HEALTHCARE AG; and BAYER AG,	)	Cause No. Division No. 1 **JURY TRIAL DEMANDED**
Defendants.	)	

PETITION[1]

COMES NOW Plaintiff, by and through the undersigned attorneys, and for Plaintiff's Petition against Defendants, JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC; JANSSEN

[1] Plaintiff and/or Plaintiff's decedent was a plaintiff in Littlejohn, et al. v. Janssen Research & Development, LLC, et al., Case No. 1422-CC10277-02, at the time this Court issued its April 3, 2018 Order severing Plaintiffs' claims. A copy of that Order is attached as an exhibit hereto.

ORTHO, LLC; JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER PHARMA AG; BAYER CORPORATION; BAYER HEALTHCARE, LLC; BAYER HEALTHCARE AG, and BAYER AG ("Defendants"), states and alleges the following upon information and belief:

1. This action is brought by Plaintiff seeking damages for personal injuries and economic damages suffered as a result of a defective and dangerous pharmaceutical product, Xarelto (rivaroxaban), which was designed, researched, developed, manufactured, tested, labeled, advertised, marketed, promoted, distributed and sold by Defendants and Defendants' representatives.

PARTIES

2. Plaintiff ROBERT CLARK on behalf of TYRONE HEMPHILL, deceased, is a citizen and resident of the State of Missouri. The Xarelto user, TYRONE HEMPHILL, resided at the time of death in the State of Missouri. Plaintiff maintains, *inter alia*, that Xarelto is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

3. Defendant JANSSEN RESEARCH & DEVELOPMENT, LLC, f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC, is a limited liability company organized under the laws of New Jersey with its principal place of business in New Brunswick, New Jersey. Defendant's sole member is JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. Defendant is the holder of the approved New Drug Application ("NDA") and supplemental NDA for Xarelto and is in the business of designing, researching, developing, manufacturing, testing, labeling, advertising, marketing, promoting, distributing and

selling pharmaceuticals, including Xarelto, for use by the mainstream public throughout the United States and the State of Missouri, including St. Louis, Missouri.

4. Defendant JANSSEN ORTHO, LLC, is a limited liability company organized under the laws of Delaware with its principal place of business in Puerto Rico. Defendant is a subsidiary of Johnson & Johnson. Its sole member is OMJ PR Holdings, which is organized under the laws of Ireland and has its principal place of business in Puerto Rico. Defendant is in the business of designing, researching, developing, manufacturing, testing, labeling, advertising, marketing, promoting, distributing and selling pharmaceuticals, including Xarelto, for use by the mainstream public throughout the United States and the State of Missouri, including St. Louis City, Missouri.

5. Defendant JANSSEN PHARMACEUTICALS, INC., f/k/a JANSSEN PHARMACEUTICA, INC., f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., is a corporation organized under the laws of Pennsylvania with its principal place of business in Titusville, New Jersey. Defendant is in the business of designing, researching, developing, manufacturing, testing, labeling, advertising, marketing, promoting, distributing and selling pharmaceuticals, including Xarelto, for use by the mainstream public throughout the United States and the State of Missouri, including St. Louis City, Missouri.

6. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC., is a corporation organized under the laws of Delaware with its principal place of business in Montville, New Jersey. Defendant, formerly known as Berlex Laboratories, Inc., and Berlex, Inc., is a U.S. subsidiary of BAYER HEALTHCARE, LLC, and is in the business of designing, researching, developing, manufacturing, testing, labeling, advertising, marketing, promoting, distributing and selling pharmaceuticals, including Xarelto, for use by the mainstream public throughout the United States and the State of Missouri, including St. Louis City, Missouri.

7. Defendant BAYER PHARMA AG, formerly known as Bayer Schering Pharma AG and Schering AG, is a pharmaceutical company domiciled in Germany with its principal place of business in Leverkusen, Germany. Defendant is in the business of designing, researching, developing, manufacturing, testing, labeling, advertising, marketing, promoting, distributing and selling pharmaceuticals, including Xarelto, for use by the mainstream public throughout the United States and the State of Missouri, including St. Louis City, Missouri.

8. Defendant BAYER CORPORATION is a corporation organized under the laws of Indiana with its principal place of business in Pittsburgh, Pennsylvania. Defendant is the sole member of BAYER HEALTHCARE, LLC, and a parent of BAYER HEALTHCARE PHARMACEUTICALS, INC. Defendant is in the business of designing, researching, developing, manufacturing, testing, labeling, advertising, marketing, promoting, distributing and selling pharmaceuticals, including Xarelto, for use by the mainstream public throughout the United States and the State of Missouri, including St. Louis, Missouri.

9. Defendant BAYER HEALTHCARE, LLC, is a limited liability company organized under the laws of Delaware with its principal place of business in Whippany, New Jersey. Defendant is in the business of designing, researching, developing, manufacturing, testing, labeling, advertising, marketing, promoting, distributing and selling pharmaceuticals, including Xarelto, for use by the mainstream public throughout the United States and the State of Missouri, including the city of St. Louis, Missouri.

10. Defendant BAYER HEALTHCARE AG is a company domiciled in Germany with its principal place of business in Leverkusen, Germany. It is the parent company of BAYER CORPORATION, BAYER HEALTHCARE, LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER PHARMA AG. Defendant is in the business of designing, researching, developing, manufacturing, testing, labeling, advertising, marketing,

promoting, distributing and selling pharmaceuticals, including Xarelto, for use by the mainstream public throughout the United States and the State of Missouri, including St. Louis, Missouri.

11. Defendant BAYER AG is a chemical and pharmaceutical company domiciled in Germany with its principal place of business in Leverkusen, Germany. It is the third largest pharmaceutical company in the world and the parent company of all other Bayer defendants. Defendant is in the business of designing, researching, developing, manufacturing, testing, labeling, advertising, marketing, promoting, distributing and selling pharmaceuticals, including Xarelto, for use by the mainstream public throughout the United States and the State of Missouri, including St. Louis, Missouri.

JURISDICTION AND VENUE

12. Defendants regularly conduct or solicit business in the State of Missouri, derive substantial revenue from goods used or consumed in the Missouri, and maintain numerous employees, agents, and servants in Missouri for the transaction of their Xarelto business in Missouri.

13. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, the Court has personal jurisdiction over the defendants, because Defendants are present in the State of Missouri such that requiring an appearance does not offend traditional notions of fair play and substantial justice. Defendants expected or should have expected that their acts and omissions described herein would have consequences throughout the United States of America and within the State of Missouri in particular.

14. This court has personal jurisdiction over the Defendants pursuant to and consistent with Missouri's long arm statute (R.S.Mo. § 506.500) and the Constitutional requirements of Due Process in that the Defendants, acting through their agents or apparent agents, committed one or more of the following:

a. The transaction of any business within the state;

b. The making of any contract within the state;

c. The commission of a tortious act within this state; and

d. The ownership, use, or possession of any real estate situated within this state.

15. Requiring Defendants to litigate this claim in Missouri does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

16. Defendants engage in a continuous and systematic course of business in the State of Missouri by designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals, including Xarelto, throughout the state. The Plaintiff's claims arise out of Defendants' design, testing, manufacture, advertising, marketing, promotion, sale, and distribution of Xarelto in the State of Missouri.

17. More particularly, the approval process for Xarelto has been seriously questioned after reviews of the clinical trial process found systemic errors. In fact, half of the clinical trial sites for Xarelto received the most severe rating from the United States Food and Drug Administration (FDA), indicating that the inspection identified objectionable conditions or practices significant enough to warrant regulatory action.

18. The Defendants decided to target Missouri as the location for numerous crucial clinical trials that ultimately led to the FDA's approval of Xarelto for sale in the United States. These trials were conducted throughout Missouri in multiple locations across the state. At these locations, the Defendants committed the wrongdoing alleged herein that proximately caused the Plaintiff's injuries, namely concealing the true safety profile of Xarelto relative to comparator drugs. Ultimately, this conduct led the Defendants to inadequately warn of the true dangers of the drug to all patients. Similarly, it was this wrongful conduct that laid the foundation for misrepresentations Defendants made in selling of tens of millions of dollars' worth of Xarelto to

Missouri Medicaid and related Missouri governmental institutions. This conduct by Defendants in Missouri directly and proximately caused the injury that forms the basis of Plaintiff's cause of action.

19. In addition, certain Plaintiffs named when this action was originally filed suffered injury from the Defendants' products in Missouri and in the City of St. Louis, Missouri. Accordingly, venue is proper under R.S.Mo. § 508.010.

20. Plaintiff seeks relief that is within the jurisdictional limits of the Court in an amount in excess of Twenty-Five Thousand Dollars ($25,000.00).

FACTUAL BACKGROUND

21. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, marketed, promoted, distributed and sold Xarelto as a safe and effective treatment to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip and knee replacement surgery.

22. After obtaining initial FDA approval, Defendants launched Xarelto in the United States in 2011.

23. Xarelto is an anticoagulant that acts as a Factor Xa inhibitor, and is available by prescription in oral tablet doses of 20mg, 15mg, and 10mg.

24. Approval of Xarelto for the prophylaxis of DVT and PE in patients undergoing hip replacement or knee replacement surgeries was based on a series of clinical trials known as the Regulation of Coagulation in Orthopedic Surgery to Prevent Deep Venous Thrombosis and Pulmonary Embolism studies (hereinafter referred to as the "RECORD" studies). The findings of the RECORD studies showed that rivaroxaban was superior to enoxaparin for thromboprophylaxis after total knee and hip arthroplasty (based on the Defendants' definition), accompanied by similar

rates of bleeding. However, the studies also showed a greater incidence with Xarelto of bleeding leading to decreased hemoglobin levels and transfusion of blood. (Lassen, M.R., et al. *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Arthroplasty.* N.Engl.J.Med. 2008;358:2776-86; Kakkar, A.K., et al. *Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty: a double-blind, randomised controlled trial.* Lancet 2008;372:31-39; Ericksson, B.I., et al. *Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Hip Arthroplasty.* N.Engl.J.Med. 2008;358:2765-75.)

25. Approval of Xarelto for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation in the U.S. was based on a clinical trial known as the Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation study (hereinafter referred to as "ROCKET AF"). The study's findings showed that rivaroxaban was noninferior to warfarin for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation, with a similar risk of major bleeding. However, "bleeding from gastrointestinal sites, including upper, lower, and rectal sites, occurred more frequently in the rivaroxaban group, as did bleeding that led to a drop in the hemoglobin level or bleeding that required transfusion." (Patel, M.R., et al. *Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation.* N.Engl.J.Med. 2011;365:883-91.)

26. Approval of Xarelto for the treatment of DVT and/or PE and the reduction in recurrence of DVT and/or PE in the U.S. was based on the clinical trials known as the EINSTEIN-DVT, EINSTEIN-PE, and EINSTEIN-Extension studies. The EINSTEIN-DVT study tested Xarelto versus a placebo, and merely determined that Xarelto offered an option for treatment of DVT, with obvious increased risk of bleeding events as compared to placebo. (The

EINSTEIN Investigators. *Oral Rivaroxaban for Symptomatic Venous Thromboembolism.* N.Engl.J.Med. 2010;363:2499-510). The EINSTEIN-Extension study confirmed that result. (Roumualdi, E., et al. *Oral rivaroxaban after symptomatic venous thromboembolism: the continued treatment study (EINSTEIN-Extension study).* Expert Rev. Cardiovasc. Ther. 2011;9(7):841-844). The EINSTEIN-PE study's findings showed that a rivaroxaban regimen was non-inferior to the standard therapy for initial and long-term treatment of PE. However, the studies also demonstrated an increased risk of adverse events with Xarelto, including those that resulted in permanent discontinuation of Xarelto or prolonged hospitalization. (The EINSTEIN-PE Investigators. *Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism.* N.Engl.J.Med. 2012;366:1287-97.)

27. Defendants use the results of the ROCKET AF study, the RECORD studies, and the EINSTEIN studies to promote Xarelto in their promotional materials, including the Xarelto website, which tout the positive results of those studies. However, Defendants' promotional materials fail to similarly highlight the increased risk of gastrointestinal bleeding and bleeding that required transfusion, among other serious bleeding concerns.

28. Defendants market Xarelto as a new oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism. Defendants emphasize the supposed benefits of treatment with Xarelto over warfarin, which they refer to as the Xarelto Difference – namely, that Xarelto does not require periodic monitoring with blood tests and does not limit a patient's diet.

29. However, in its QuarterWatch publication for the first quarter of the 2012 fiscal year, the Institute for Safe Medication Practices ("ISMP") noted that, even during the approval process, FDA "[r]eviewers also questioned the convenient once-a-day dosing scheme [of Xarelto], saying blood level studies had shown peaks and troughs that could be eliminated by

twice-a-day dosing."

30. Importantly, there is no antidote to Xarelto, unlike warfarin. Therefore, in the event of hemorrhagic complications, there is no available reversal agent. The original U.S. label approved when the drug was first marketed in the U.S. did not contain a warning regarding the lack of antidote, but instead only mentioned this important fact in the overdosage section.

31. Defendants spent significant money in promoting Xarelto, which included at least $11,000,000.00 spent during 2013 alone on advertising in journals targeted at prescribers and consumers in the U.S. In the third quarter of the 2013 fiscal year, Xarelto was the number one pharmaceutical product advertised in professional health journals based on pages and dollars spent.

32. As a result of Defendants' aggressive marketing efforts, in its first full year of being on the market, Xarelto garnered approximately $582 million in sales globally.

33. Defendants' website for Xarelto claims that over seven million people worldwide have been prescribed Xarelto. In the U.S., approximately 1 million Xarelto prescriptions had been written by the end of 2013.

34. During the Defendants' 2012 fiscal year, Xarelto garnered approximately $658 million in sales worldwide. Then, in 2013, sales for Xarelto increased even further to more than clear the $1 billion threshold commonly referred to as "blockbuster" status in the pharmaceutical industry, ultimately reaching approximately $2 billion for the fiscal year. Thus, Xarelto is now considered the leading anticoagulant on a global scale in terms of sales.

35. As part of their marketing of Xarelto, Defendants widely disseminated direct-to consumer advertising campaigns that were designed to influence patients, including Plaintiff, to make inquiries to their prescribing physician about Xarelto and/or request prescriptions for Xarelto.

36. In the course of these direct to consumer advertisements, Defendants overstated the efficacy of Xarelto with respect to preventing stroke and systemic embolism, failed to adequately disclose to patients that there is no drug, agent, or means to reverse the anticoagulation effects of Xarelto, and that such irreversibility could have permanently disabling, life-threatening and fatal consequences.

37. On June 6, 2013, Defendants received an untitled letter from the FDA's Office of Prescription Drug Promotion (hereinafter referred to as the "OPDP") regarding its promotional material for the atrial fibrillation indication, stating that, "the print ad is false or misleading because it minimizes the risks associated with Xarelto and makes a misleading claim" regarding dose adjustments, which was in violation of FDA regulations. The OPDP thus requested that Defendants immediately cease distribution of such promotional material.

38. Prior to Plaintiff's prescription of Xarelto, Plaintiff became aware of the promotional materials described herein.

39. Prior to Plaintiff's prescription of Xarelto, Plaintiff's prescribing physician received promotional materials and information from sales representatives of Defendants that Xarelto was just as effective as warfarin in reducing strokes in patients with non-valvular atrial fibrillation, as well as preventing DVT/PE in patients with prior history of DVT/PE or undergoing hip or knee replacement surgery, and was more convenient, without also adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Xarelto.

40. Defendants also failed to warn emergency room doctors, surgeons, and other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding in users of warfarin, there is no effective agent to reverse the anticoagulation

effects of Xarelto, and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Xarelto.

41. The Xarelto Medication Guide, prepared and distributed by Defendants and intended for U.S. patients to whom Xarelto has been prescribed, failed to warn and disclose to patients that there is no agent to reverse the anticoagulation effects of Xarelto and that if serious bleeding occurs, it may be irreversible, permanently disabling, and life-threatening.

42. In the year leading up to June 30, 2012, there were 1,080 Xarelto-associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the FDA, including at least 65 deaths. Of the reported hemorrhage events associated with Xarelto, 8% resulted in death, which was approximately twofold the risk of a hemorrhage-related death with warfarin.

43. At the close of the 2012 fiscal year, a total of 2,081 new Xarelto-associated SAE reports were filed with the FDA in its first full year on the market, ranking tenth among other pharmaceuticals in direct reports to the FDA. Of those reported events, 151 resulted in death, as compared to only 56 deaths associated with warfarin.

44. The ISMP referred to these SAE figures as constituting a "strong signal" regarding the safety of Xarelto, defined as "evidence of sufficient weight to justify an alert to the public and the scientific community, and to warrant further investigation."

45. Of particular note, in the first quarter of 2013, the number of reported serious adverse events associated with Xarelto (680) overtook that of Pradaxa (528), another new oral anticoagulant, which had previously ranked as the number one reported drug in terms of adverse events in 2012.

46. Moreover, on a global scale, in the first eight months of 2013, German regulators received 968 Xarelto-related adverse event reports, including 72 deaths, as compared to a total of 750 reports and 58 deaths in 2012.

47. Despite the clear signal generated by the SAE data, Defendants failed to either alert the public and the scientific community, or perform further investigation into the safety of Xarelto.

48. Defendants:

(a) failed to investigate, research, study and define, fully and adequately, the safety profile of Xarelto;

(b) failed to provide adequate warnings about the true safety risks associated with the use of Xarelto;

(c) failed to provide adequate warning regarding the pharmacokinetic and pharmacodynamic variability of Xarelto and its effects on the degree of anticoagulation in a patient;

(d) failed to provide adequate warning that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Xarelto;

(e) failed to disclose in the "Warnings" Section that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto;

(f) failed to advise prescribing physicians, such as the Plaintiff's physician, to instruct patients that there was no agent to reverse the anticoagulant effects of Xarelto;

(g) failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Xarelto;

(h) failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Xarelto users;

(i) failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Xarelto, especially, in those patients

with a prior history of gastrointestinal issues and/or upset;

(j) failed to provide adequate warnings regarding the increased risk of suffering a bleeding event, requiring blood transfusions in those taking Xarelto;

(k) failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Xarelto and to continue testing and monitoring of renal functioning periodically while the patient is on Xarelto;

(l) failed to provide adequate warnings regarding the need to assess hepatic functioning prior to starting a patient on Xarelto and to continue testing and monitoring of hepatic functioning periodically while the patient is on Xarelto;

(m) failed to include a boxed warning about serious bleeding events associated with Xarelto;

(n) failed to include a bolded warning about serious bleeding events associated with Xarelto; and

(o) in their "Medication Guide" intended for distribution to patients to whom Xarelto has been prescribed, Defendants failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Xarelto and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences.

49. At all times relevant, Defendants had a duty to exercise reasonable care in the researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing and marketing of Xarelto for distribution, sale and use by the general public, including Plaintiff, and to ensure that Xarelto's use did not result in avoidable injuries.

50. During the entire time Xarelto has been on the market in the United States, FDA regulations required Defendants to revise their product labeling "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with the drug; a causal relationship need not have been definitely established." 21 C.F.R. 201.57(c)(6)(i). This regulation allowed defendants to issue such a warning without prior FDA approval.

51. During the years since first marketing Xarelto in the U.S., Defendants modified the U.S. labeling and prescribing information for Xarelto, which included additional information regarding the use of Xarelto in patients taking certain medications. Despite being aware of: (1) serious, and sometimes fatal, irreversible bleeding events associated with the use of Xarelto; and (2) 2,081 SAE Medwatch reports filed with the FDA in 2012 alone, including at least 151 deaths, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed above.

52. Prior to applying for and obtaining approval of Xarelto, Defendants knew or should have known that consumption of Xarelto was associated with and/or would cause the induction of life-threatening bleeding, and Defendants possessed at least one clinical scientific study, which evidence Defendants knew or should have known was a signal that life-threatening bleeding risk needed further testing and studies prior to its introduction to the market.

53. Upon information and belief, despite life-threatening bleeding findings in a clinical trial and other clinical evidence, Defendants failed to adequately conduct complete and proper testing of Xarelto prior to filing their New Drug Application for Xarelto.

54. Upon information and belief, from the date Defendants received FDA approval to market Xarelto, Defendants made, distributed, marketed, and sold Xarelto without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Xarelto was associated with and/or

could cause life-threatening bleeding, presented a risk of life-threatening bleeding in patients who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Xarelto with regard to severe side effects, specifically life-threatening bleeding.

55. Upon information and belief, Defendants concealed and failed to completely disclose its knowledge that Xarelto was associated with or could cause life-threatening bleeding as well as its knowledge that they had failed to fully test or study said risk.

56. Upon information and belief, Defendants ignored the association between the use of Xarelto and the risk of developing life-threatening bleeding.

57. Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Xarelto for life-threatening bleeding risk further rendered warnings for this medication inadequate.

58. When warning of safety and risks of Xarelto, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as the "FDA"), to Plaintiff and the public in general, that Xarelto had been tested and was found to be safe and/or effective for its indicated use.

59. Defendants concealed their knowledge of Xarelto's defects from Plaintiff, the FDA, the public in general, and/or the medical community specifically.

60. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Xarelto for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, to treat DVT and PE, to reduce the risk of recurrence of DVT and/or PE, and for prophylaxis of DVT for patients undergoing hip

and knee replacement surgery, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

61. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Xarelto during clinical trials, forcing Plaintiff, and Plaintiff's physicians, hospitals, and/or the FDA, to rely on safety information that applies to other non-valvular atrial fibrillation treatment and DVT/PE treatment and prophylaxis, which does not entirely and/or necessarily apply to Xarelto whatsoever.

62. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer serious and dangerous side effects including, *inter alia*, life-threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, expenses for hospitalization and medical treatment, and loss of earnings. Plaintiff herein has sustained certain of the above health consequences due to Plaintiff's use of Xarelto.

63. Defendants concealed their knowledge of the defects in their products from the Plaintiff, and Plaintiff's physicians, hospitals, pharmacists, the FDA, and the public in general.

64. The foregoing allegations, those that follow, and those facts to be proven at trial establish that Defendants acted affirmatively, through active and intentional fraudulent omission, concealment, and suppression of the safety dangers associated with their drug, Xarelto, to conceal from Plaintiff the existence of Plaintiff's cause of action, and such concealment by Defendants in fact lulled, induced, or otherwise prevented Plaintiff from discovering the existence of Plaintiff's various causes of action.

65. Defendants are estopped from asserting any statute of limitations defense because they fraudulently concealed from Plaintiff and the medical community the nature of Plaintiff's injuries and their connection with Xarelto.

COUNT I
STRICT PRODUCT LIABILITY

66. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

67. The Xarelto manufactured and/or supplied by Defendants was unaccompanied by proper warnings regarding all possible adverse side-effects and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. Defendants failed to perform adequate testing in that adequate testing would have shown that Xarelto possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made. Had the testing been adequately performed, the product would have been allowed to enter the market, if at all, only with warnings that would have clearly and completely identified the risks and dangers of the drug.

68. The Xarelto manufactured and/or distributed and/or supplied by Defendants was defective due to inadequate post-marketing warning or instruction because Defendants failed to provide adequate warnings to users or consumers of Xarelto and continued to aggressively promote Xarelto.

69. As the proximate cause and legal result of the defective condition of Xarelto as manufactured and/or supplied and/or distributed by Defendant, and as a direct and legal result of the conduct of Defendants described herein, Plaintiff has been damaged.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT II
STRICT PRODUCT LIABILITY
(Pursuant to Restatement Second of Torts 402a (1965))

70. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

71. The Xarelto manufactured and/or distributed and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design and formulation of the drug.

72. Alternatively, the Xarelto manufactured and/or distributed and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than alternative drugs available for the treatment of Plaintiff's condition.

73. There existed, at all times material hereto, safer alternative medications.

74. Defendants did not perform adequate testing upon Xarelto. Adequate testing would have revealed that Xarelto causes serious adverse effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and severity should have been made.

75. The Xarelto manufactured, designed, marketed, distributed and/or sold by Defendants was unaccompanied by proper and adequate warnings regarding adverse effects associated with the use of Xarelto, and the severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of adverse effects and did not accurately relate the lack of efficacy.

76. Defendants did not warn the FDA of material facts regarding the safety and efficacy of Xarelto, which facts Defendants knew or should have known.

77. The Xarelto manufactured and/or distributed and/or supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risk of injury from Xarelto, they failed to provide adequate warnings to users or consumers of Xarelto and continued to promote Xarelto.

78. As a result of the defective condition of Xarelto, Plaintiff has suffered damages and injury.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT III
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

79. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

80. The acts, omissions, and representations of Defendants regarding the manufacturing, distribution and marketing of Xarelto as described in the foregoing paragraphs were intentional, reckless, extreme and outrageous. Defendants intentionally engaged in extreme and outrageous conduct when they intentionally and/or recklessly marketed Xarelto and then intentionally and/or recklessly concealed material information about Xarelto's potential serious adverse effects from Plaintiff and Plaintiff's physicians, hospitals, and medical providers.

81. Defendants knew that Plaintiff would suffer mental distress and anxiety upon learning that Xarelto possessed a likelihood of serious adverse effects and complications such as life-threatening bleeds.

82. As a result of defendant's misconduct, Plaintiff sustained and will continue to sustain emotional and mental distress and anxiety.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT IV
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

83. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

84. Defendants negligently and carelessly manufactured, sold, and distributed Xarelto to Plaintiff which was defective.

85. Defendants negligently and carelessly concealed the defective nature of Xarelto from Plaintiff, Plaintiff's physicians, hospitals, and medical providers.

86. Defendants negligently and carelessly misrepresented the usefulness, quality and safety of Xarelto to Plaintiff, Plaintiff's physicians, hospitals, and medical providers.

87. Defendant's negligence and carelessness directly impacted the Plaintiff in that he was induced to purchase and ingest the defective and dangerous Xarelto.

88. As a direct result of defendant's misconduct alleged herein, Plaintiff has suffered and will continue to suffer emotional and mental distress and anxiety from the fear of knowing there is a likelihood of serious adverse effects and complications of Xarelto use such as life-threatening bleeds.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT V
COMMON LAW FRAUD

89. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

90. Defendants made material representations that were false and that were either known to be false when made or were asserted without knowledge of their truth. Defendants had in its possession adverse drug event reports, drug studies, and other documentation about Xarelto and yet made the following misrepresentations:

a. Misrepresentations regarding the frequency of Xarelto-related adverse event reports or occurrences in the Xarelto label, package insert or PDR label;

b. Misrepresentations as to the existence, occurrence and frequency of occurrences, severity and extent of the overall risks of Xarelto;

c. Misrepresentations as to the efficacy of Xarelto;

d. Misrepresentations as to the number of adverse events and deaths reported with the use of Xarelto;

e. Misrepresentations regarding the nature, seriousness, and severity of adverse events reported with the use of Xarelto.

91. Defendants intended that these misrepresentations be relied upon by physicians, including Plaintiff's physicians, healthcare providers and consumers. Plaintiff did rely upon the misrepresentations that caused Plaintiff's injuries.

92. Defendant's misrepresentations were the proximate and/or producing cause of Plaintiff's injuries.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT VI

NEGLIGENCE

93. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

94. Defendants owed Plaintiff legal duties in connection with their development, manufacture, and distribution of Xarelto. Defendants breached those duties, proximately causing Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Xarelto. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

a. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Xarelto;

b. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Xarelto in unsafe doses;

c. Failure to use reasonable care in testing and inspecting Xarelto so as to ascertain whether or not it was safe for the purpose for which it was designed, manufactured and sold;

d. Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Xarelto;

e. Failure to use reasonable care in the process of manufacturing Xarelto in a reasonably safe condition for the use for which it was intended;

f. Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using Xarelto in unsafe doses; and

g. Such further acts and/or omissions that may be proven at trial.

95. The above-described acts and/or omissions of Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT VII
NEGLIGENT MISREPRESENTATION

96. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

97. Defendants failed to communicate to Plaintiff and/or the general public that the ingestion of Xarelto could cause serious injuries after they became aware of such risks. Instead, Defendants represented in its marketing that Xarelto was safe and effective.

98. Plaintiff brings this cause of action against Defendants under the theory of negligent misrepresentation for the following reasons:

a. Defendants, individually, and through their agents, representatives, distributors and/or employees, negligently misrepresented material facts about Xarelto in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;

b. The above misrepresentations were made to Plaintiff as well as the general public;

c. Plaintiff and Plaintiff's healthcare providers justifiably relied on Defendants' misrepresentations; and

d. Consequently, Plaintiff ingested Xarelto to Plaintiff's detriment. Defendants' negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT VIII
FRAUDULENT MISREPRESENTATION

99. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

100. Defendants are engaged in the business of selling Xarelto. By its advertising, labels, or otherwise, Defendants have made to Plaintiff and the public a misrepresentation of a material fact concerning the character or quality of Xarelto.

101. Plaintiff justifiably relied on Defendants' misrepresentations in purchasing Xarelto. Plaintiff has suffered physical harm proximately caused by Defendants' misrepresentations regarding the character or quality of Xarelto.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT IX

EXPRESS WARRANTY

102. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

103. Defendants are merchants and/or sellers of Xarelto. Defendants sold Xarelto to consumers, including Plaintiff, for the ordinary purpose for which such drugs are used by consumers. Defendants made representations to Plaintiff about the quality or characteristics of Xarelto by affirmation of fact, promise and/or description. The representations by Defendants became part of the basis of the bargain between Defendants and Plaintiff. Xarelto did not comport with the representations made by Defendants in that it was not safe for the use for which it was marketed. This breach of duty by Defendants was a proximate cause of the injuries and monetary loss suffered by Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT X
IMPLIED WARRANTY

104. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

WARRANTY OF MERCHANTABILITY

105. Defendants are merchants and/or sellers of Xarelto. Plaintiff purchased Xarelto from Defendants and used Xarelto for the ordinary purpose for which it is used by consumers. At the time it was purchased by Plaintiff, Xarelto was not fit for the ordinary purpose for which such drugs are used. Xarelto was not fit for the ordinary purpose for which such drugs are used because it was not manufactured, designed or marketed in a manner to accomplish its purpose safely.

Defendants' breach of its implied warranty of merchantability caused Plaintiff's injuries and monetary losses.

WARRANTY OF FITNESS

106. Defendants sold Xarelto to Plaintiff with the knowledge that Plaintiff was purchasing Xarelto for a particular purpose. Further, Defendants knew, or should have known, that Plaintiff was relying on Defendants' skill or judgment to select goods fit for Plaintiff's purpose.

107. Defendants delivered goods that were unfit for Plaintiff's particular purpose and thus breached its implied warranty of fitness. Defendants' failure to select and sell a product which was reasonably safe for its intended use proximately caused Plaintiff's injuries and monetary losses.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT XI
WRONGFUL DEATH

108. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein, and further alleges:

109. That this action is brought pursuant to § 537.080.1 R.S.Mo.

110. That as a direct and proximate result of one or more of the aforesaid acts or omissions of the Defendants complained of here and above, Plaintiff's decedent was caused to suffer great physical and mental anguish, became liable for large sums of monies for hospital, medical and other health care services, and ultimately suffered death; and decedent's heirs were caused to experience great grief, sorrow, and mental suffering, and by reason of the decedent's

death, have been caused to incur substantial funeral and burial expenses, and have been deprived of decedent's means of support and have lost decedent's companionship and society.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT XII
SURVIVAL ACTION

111. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein, and further alleges:

112. That this action is brought pursuant to § 537.020 R.S.Mo.

113. That as a direct and proximate result of one or more of the aforesaid acts or omissions of the Defendants complained of here and above, Plaintiff's decedent, prior to death, suffered severe injuries, suffered severe pain, both mental and physical, incurred substantial medical bills, lost income, was prevented from attending to decedent's normal affairs, and suffered impairment of the enjoyment of life, until the date of death.

WHEREFORE, Plaintiff demands judgment against Defendants in a sum in excess of $25,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained

by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants, whose actions and omissions were outrageous because of Defendants' evil motives and reckless indifference to the rights of others and showed complete indifference to or a conscious disregard for the safety of others, in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff's attorney's fees;

4. Awarding Plaintiff the costs of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

6. Plaintiff hereby demands trial by jury as to all issues.

Respectfully submitted,

THE DRISCOLL FIRM, P.C.

BY: */s/ John J. Driscoll*

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was e-filed and served via this Court's electronic delivery system on all counsel of record this 6th day of April 2018.

/s/ John J. Driscoll